

In The Claims:

Claim 1. (currently amended) A biopolymer marker [selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 or at least one analyte thereof useful in indicating at least one particular disease state] peptide consisting of SEQ ID NO:1 diagnostic for insulin resistance.

Claims 2-38. (currently canceled).

Claim 39. (new) A method for diagnosing insulin resistance comprising:

- (a) obtaining a sample from a patient;
- (b) conducting mass spectrometric analysis on said sample in a manner effective to maximize elucidation of discernible peptide fragments contained therein; and
- (c) comparing mass spectrum profiles of a peptide consisting of SEQ ID NO:1 to mass spectrum profiles of peptides elucidated from said sample; wherein recognition of a mass spectrum profile in the sample displaying the characteristic profile of the mass spectrum profile for the peptide consisting of SEQ ID NO:1 is diagnostic for insulin resistance.
- A1

Claim 40. (new) The method of claim 39, wherein the sample is an unfractionated body fluid or a tissue sample.

Claim 41. (new) The method of claim 39, wherein said sample is selected from the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

Claim 42. (new) The method of claim 39, wherein said mass spectrometric analysis is selected from the group consisting of Surface Enhanced Laser Desorption Ionization (SELDI) mass spectrometry (MS), Maldi Qq TOF, MS/MS, TOF-TOF, ESI-Q-TOF and ION-TRAP.

Claim 43. (new) The method of claim 39, wherein said patient is a human.

Claim 44. (new) An insulin resistance diagnostic kit comprising: (a) a peptide consisting of SEQ ID NO:1 and (b) an antibody that binds to said peptide in a sample from a patient.  
*(A1  
cont'd)*

Claim 45. (new) The diagnostic assay kit of claim 44, wherein said antibody is immobilized on a solid support.

Claim 46. (new) The diagnostic kit of claim 44, wherein said antibody is labeled.

Restriction

Restriction to one of the following inventions has been required under 35 USC 121:

- I. Claims 1-2, drawn to a biopolymer marker, comprising SEQ ID NO:1, classified in class 530, subclass 300.
- II. Claims 1-2, drawn to a biopolymer marker, comprising SEQ ID NO:2, classified in class 530, subclass 300.
- III. Claims 1-2, drawn to a biopolymer marker, comprising SEQ ID NO:3, classified in class 530, subclass 300.
- IV. Claims 3-9, drawn to a method for categorizing a disease state, classified in class 424, subclass 93.1.
- V. Claims 10-28, drawn to a diagnostic assay kit, classified in class 422, subclass 61.
- VI. Claims 29-32, drawn to polyclonal antibodies, classified in class 436, subclass 547.
- VII. Claims 33-37, drawn to a method for identifying a therapeutic process related to a disease state, classified in class 435, subclass 7.1.
- VIII. Claim 38, drawn to a method for regulating a disease state, classified in class 435, subclass 7.1.

Election and Request For Rejoining Claims

Applicants here elect without traverse Group I (claims 1 and 2, as drawn to a biopolymer marker comprising SEQ ID NO:1) for prosecution on the merits.

The instant application is related in claim format to several pending applications of which serial number 09/846,352 is exemplary. The biopolymer marker of serial number 09/846,352 was found to be novel and subsequently claims reading on methods and kits limited to its use were rejoined with the claims reading on the biopolymer marker under *Ochai*. Similarly, if SEQ ID NO:1 of the instant application is found to be novel, methods and kits limited to its use should also be novel. Thus, in an effort to maintain equivalent scope in all of these applications, Applicants respectfully request that the Examiner enter the new claims (39-46) added herein by amendment and consider rejoining them with claims reading on the biopolymer marker of SEQ ID NO:1 when such claims are found allowable.

Claim Status/Support For Claim Amendments

Claim 1 has been amended. Claims 2-38 have been canceled. Claims 39-46 have been added. Claims 1 and 39-46 are pending in the instant application.

No new matter has been added by the amendments to the specification.

According to MPEP 2422.02, the sequence identifier for sequences present in the drawings must be used either in the drawing itself or in the Brief Description of the Drawings.

Applicants have herein amended the specification at the Brief Description of the Drawings section to include sequence identifiers for all sequences disclosed in the drawings.

Several protocols in the experimental section of the detailed description have been amended to properly identify the trademark SEPHAROSE.

The abstract has been amended to remove the legal phraseology ("said").

No new matter has been added by the addition of new claims 39-46. The subject matter of new claims 39-46 corresponds to subject matter originally found in canceled claims 2-38. The above additions to the claims find basis in the original disclosure at page 25, line 16 to page 26, line 22. The method of new claim 39 is described in detail at pages 37-47. Page 47, line 21 to page 48, line 2 refers to use of various types of samples and page 38, line 21 to page 39, line 1 refers to different mass spectrometric techniques. Page 46, line 21 refers to practicing the claimed methods with a human patient. Pages 47-48 describe kits contemplated for use with the claimed methods. Page 47, lines 19-20, refers particularly to the immobilizing on solid supports and labeling of components of the contemplated kits. It is clear from

these specific recitations and from the description of methods utilized that the methods and types of kits recited in the newly added claims (39-46) were fully contemplated by the inventors at the time of filing and were enabled by virtue of the disclosure as originally filed.

**Sequence Compliance**

The Examiner attached a Notice To Comply (regarding the sequence rules) to the Office Action mailed on July 15, 2003. It is noted that Applicants previously submitted both a computer readable form (CRF) and a paper copy of the Sequence Listing with a Preliminary Amendment filed on April 19, 2002. A copy of this filing along with the stamped postcard (April 23, 2002) indicating that the PTO received the filing is included with the instant Response for the convenience of the Examiner. Applicants respectfully request that the Examiner confirm that the Preliminary Amendment dated April 19, 2002 was entered into the instant application.

However, in the event that the originally filed Sequence Listing has been misplaced, Applicants include herein both a substitute computer readable form (CRF) and a substitute paper copy of the Sequence Listing (as it appears on the diskette) to replace those filed on April 19, 2002. The substitute Sequence Listing is identical in content to the originally filed Sequence Listing; it

is submitted as a replacement copy. The peptide sequences listed in the Sequence Listing were disclosed at page 46, lines 8-11 of the instant specification as originally filed. Thus, no new matter has been added by the Sequence Listing. The computer readable form (CRF) of the substitute Sequence Listing submitted herewith is identical to the paper copy of the substitute Sequence Listing submitted herewith.